UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

03 DEC 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: New Chemical Registration Standard:
Lactic Acid - Submission of Data
Evaluation Records

FROM: Allen W. Vaughan, Entomologist Allen W. Vaughan 12-2-87
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

THRU: for Norman J. Cook, Head, Section II Allen W. Vaughan 12-2-87
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

THRU: Henry T. Craven, Acting Chief Henry T. Craven 12-2-87
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

TO: Robert J. Taylor, PM 25
Fungicide-Herbicide Branch
Registration Division (TS-767C)

On September 24, 1987, EEB submitted the lactic acid Registration Standard to RD. The cover memo indicated that the Data Evaluation Records would be submitted at a later date. Attached are the DER's which were completed by EEB in support of the lactic acid standard.

Attachments

cc: B. Lowery (MSS/HED)
H. Jacoby (SIS/HED)

DATA EVALUATION RECORD

1. Chemical: Lactic acid (Propel)

2. Test Material: SY-83, 80% ai

3. Study Type: Acute Toxicity Test for Freshwater Fish

   Species tested: Bluegill sunfish, Lepomis macrochirus

4. Study ID: Forbis, A.D., D. Burgess, and L.Georgie. 1984. Static Acute Toxicity Report #32146. Acute toxicity of SY-83 to bluegill sunfish, Lepomis macrochirus. Prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO. Submitted by Brea Agricultural Service, Inc., Stockton, CA. EPA Reg. No. 9018-A. EPA Acc. No. 265651.

5. Reviewed By: Allen W. Vaughan
   Entomologist
   EEB/HED
   Signature: Allen W. Vaughan
   Date: 11.13.87

6. Approved By: Norman Cook
   Supervisory Biologist
   EEB/HED
   Signature: Norman Cook
   Date: 12.1.87

7. Conclusions:

This study is scientifically sound, and shows the 96-hour LC_{50} for SY-83 (80% ai) to bluegill sunfish to be 130 mg/l. This value indicates SY-83 is practically nontoxic to freshwater fish.

This study fulfills the Guideline requirement for an acute toxicity test on a freshwater fish.

8. Recommendations: N/A

9. Background:

This study was submitted in support of registration.

10. Discussion of Individual Studies: N/A.

11. Materials and Methods:

a. Test animals were bluegills obtained from Osage Catfisheries in Osage Beach, MO. The fish had a mean weight of 0.37 gm and a mean standard length of 24 mm at test termination.

b. Test System: 5-gal glass vessels were used as test chambers. 15 l of water was used per vessel. Ten fish were used for each exposure level. The controls consisted of the same number of fish and the same volume of water without the test material. Both the range finding and definitive tests were performed at 22° +/- 1°C.

A range finding test was performed to establish test concentrations for the definitive test. The fish were exposed to concentrations of 10 and 100 mg/l under static conditions. Five fish were exposed to each concentration for a period of 96 hr.

Ten fish per vessel were used in the definitive test. Test fish were exposed to five concentrations of the test compound for 96 hr. The concentrations used for the definitive test were based on the results obtained from the range finding tests. A culture in dilution water without the test chemical was used as the control. Each vessel was checked once every 24 hr for mortality and abnormal effects such as surfacing, loss of equilibrium, and dark discoloration.

Dissolved oxygen, temperature, and pH were measured throughout the test in the control vessels and the 56 mg/l test vessels.

c. Dose: Static bioassay using nominal concentrations; no solvent used.

d. Design: Five concentrations (56, 100, 180, 320, and 560 ppm), plus control.

e. Statistics: A 96-hr LC_{50} value was determined along with 95% confidence limits; the binomial method was used.

12. Reported Results:

The 96-hour LC_{50} = 130 mg/L for 80% ai SY-83 and bluegill sunfish.

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13. Study Authors' Conclusions/OA Measures:

96-hour LC_{50} = 130 mg/L (95% C.I. = 100 to 180 mg/l). The study was conducted following the intent of the GLP Regulations and the final report was reviewed by ABC Laboratories' Ouality Assurance Unit.

14. Reviewer's Discussion and Interpretation of the Study:

a. Test Procedures: Procedures were in accordance with protocols recommended in the Guidelines and in the HED Standard Evaluation Procedure for the freshwater fish acute study. There were no problems in this regard.

b. Statistical Analysis: Analyses conducted by the authors were identical to the methods used by EEB to analyze this type of data. Independent validation (see attached sheet) confirms that analyses were appropriate.

c. Discussion/Results: This study shows the following values for SY-83 (80% ai) effect on bluegills:

96-hour LC_{50} = 130 mg/l (practically nontoxic)
96-hour NOEL = 56 mg/l

d. Adequacy of Study:

1. Classification: Core

2. Rationale: SEP protocol; no major deviations noted.

3. Reparability: N/A

15. Completion of One-Liner for Study: Yes

16. CBI Appendix: N/A.

DATA EVALUATION RECORD

1. Chemical: Lactic acid (Propel)

2. Test Material: SY-83, 80% ai

3. Study Type: Acute Toxicity Test for Freshwater Fish

   Species tested: Rainbow trout, *Salmo gairdneri*

4. Study ID: Forbis, A.D., D. Burgess, and L.Georgie. 1984. Static Acute Toxicity Report #32147. Acute toxicity of SY-83 to rainbow trout (*Salmo gairdneri*). Prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO. Submitted by Brea Agricultural Service, Inc., Stockton, CA. EPA Reg. No. 9018-A. EPA Acc. No. 265652.

5. Reviewed By: Allen W. Vaughan, Entomologist, EEB/HED — Signature: Allen W. Vaughan — Date: 11.13.87

6. Approved By: Norman Cook, Supervisory Biologist, EEB/HED — Signature: Norman Cook — Date: 12.1.87

7. Conclusions:

This study is scientifically sound, and shows the 96-hour LC_{50} for SY-83 (80% ai) to rainbow trout to be 130 mg/l. This value indicates SY-83 is practically nontoxic to freshwater fish.

This study fulfills the Guideline requirement for an acute toxicity test on a freshwater fish.

8. Recommendations: N/A

9. Background:

This study was submitted in support of registration.

10. Discussion of Individual Studies: N/A.

11. Materials and Methods:

a. Test animals were rainbow trout obtained from Trout Lodge in McMillan, WA. The trout had a mean weight of 1.09 gm and a mean standard length of 42 mm at test termination.

b. Test System: 5-gal glass vessels were used as test chambers. 15 l of water was used per vessel. Ten fish were used for each exposure level. The controls consisted of the same number of fish and the same volume of water without the test material. Both the range finding and definitive tests were performed at 12° +/- 1°C.

A range finding test was performed to establish test concentrations for the definitive test. The fish were exposed to concentrations of 1.0, 10, and 100 mg/l under static conditions. Five fish were exposed to each concentration for a period of 96 hr.

Ten trout per vessel were used in the definitive test. Test fish were exposed to five concentrations of the test compound for 96 hr. The concentrations used for the definitive test were based on the results obtained from the range finding tests. A culture in dilution water without the test chemical was used as the control. Each vessel was checked once every 24 hr for mortality and abnormal effects such as surfacing, loss of equilibrium, and dark discoloration.

Dissolved oxygen, temperature, and pH were measured throughout the test in the control vessels and the 32 mg/l test vessels.

c. Dose: Static bioassay using nominal concentrations; no solvent used.

d. Design: Five concentrations (32, 56, 100, 180, and 320 ppm), plus control.

e. Statistics: A 96-hr LC_{50} value was determined along with 95% confidence limits; the binomial method was used.

12. Reported Results:

The 96-hour LC_{50} = 130 mg/L for 80% ai SY-83 and rainbow trout.

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13. Study Authors' Conclusions/QA Measures:

96-hour LC_{50} = 130 mg/L (95% C.I. = 100 to 180 mg/l). The study was conducted following the intent of the GLP Regulations and the final report was reviewed by ABC Laboratories' Ouality Assurance Unit.

14. Reviewer's Discussion and Interpretation of the Study:

a. Test Procedures: Procedures were in accordance with protocols recommended in the Guidelines and in the HED Standard Evaluation Procedure for the freshwater fish acute study. There were no problems in this regard.

b. Statistical Analysis: Analyses conducted by the authors were identical to the methods used by EEB to analyze this type of data. Independent validation (see attached sheet) confirms that analyses were appropriate.

c. Discussion/Results: This study shows the following values for SY-83 (80% ai) effect on rainbow trout:

96-hour LC_{50} = 130 mg/l (practically nontoxic)
96-hour NOEL = 56 mg/l

d. Adequacy of Study:

1. Classification: Core

2. Rationale: SEP protocol; no major deviations noted.

3. Reparability: N/A

15. Completion of One-Liner for Study: Yes

16. CBI Appendix: N/A.

DATA EVALUATION RECORD

1. Chemical: Lactic acid (Propel)

2. Test Material: SY-83, 80% ai

3. Study Type: Acute Toxicity Test for Freshwater Aquatic Invertebrate

   Species tested: Daphnia magna

4. Study ID: Forbis, A.D., D. Burgess, and L.Georgie. 1984. Static Acute Toxicity Report #32148. Acute toxicity of SY-83 to Daphnia magna. Prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO. Submitted by Brea Agricultural Service, Inc., Stockton, CA. EPA Reg. No. 9018-A. EPA Acc. No. 265648.

5. Reviewed By: Allen W. Vaughan
   Entomologist
   EEB/HED
   Signature: Allen W. Vaughan
   Date: 11.13.87

6. Approved By: Norman Cook
   Supervisory Biologist
   EEB/HED
   Signature: Norman Cook
   Date: 12.1.87

7. Conclusions:

This study is scientifically sound, and shows the 48-hour LC_{50} for SY-83 (80% ai) to Daphnia magna to be 750 mg/l. This value indicates SY-83 is practically nontoxic to aquatic invertebrates.

This study fulfills the Guideline requirement for an acute toxicity test on a freshwater invertebrate.

8. Recommendations: N/A

9. Background:

This study was submitted in support of registration.

10. Discussion of Individual Studies: N/A.

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11. Materials and Methods:

a. Test animals were first instar D. magna cultured in the laboratory.

b. Test System: 250 ml beakers were used as test chambers. 200 ml of water was used per beaker. Duplicate cultures were used for the exposure and controls. The controls consisted of the same number of daphnids and the same volume of water without the test material. Both the range finding and definitive tests were performed at 20° +/- 2°C.

A range finding test was performed to establish test concentrations for the definitive test. The daphnids were exposed to concentrations of 1.0, 10, and 100 mg/l under static conditions. Ten daphnids were exposed to each concentration for a period of 48 hr.

Ten daphnids per beaker were used in the definitive test. Duplicate cultures of daphnids were exposed to five concentrations of the test compound for 48 hr. The concentrations used for the definitive test were based on the results obtained from the range finding tests. Duplicate cultures in dilution water without the test chemical were used as controls. Each chamber was checked for immobilized daphnids at 24 and 48 hr after initiation of the test.

Dissolved oxygen, temperature, and pH were measured at the beginning of the test in the control beakers and at 48 hr in all the beakers.

c. Dose: Static bioassay using nominal concentrations; no solvent used.

d. Design: Five concentrations (100, 180, 320, 560, and 1000 ppm), plus control.

e. Statistics: A 48-hr LC_{50} value was determined along with 95% confidence limits; the binomial method was used.

12. Reported Results:

The 48-hour LC_{50} = 720 mg/L for 80% ai SY-83 and first instar D. magna.

13. Study Authors' Conclusions/QA Measures:

48-hour LC_{50} = 720 mg/L (95% C.I. = 560 to 1000 mg/l).

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The study was conducted following the intent of the GLP Regulations and the final report was reviewed by ABC Laboratories' Quality Assurance Unit.

14. Reviewer's Discussion and Interpretation of the Study:

a. Test Procedures: Procedures were in accordance with protocols recommended in the Guidelines and in the HED Standard Evaluation Procedure for the freshwater invertebrate acute study. There were no problems in this regard.

b. Statistical Analysis: Analyses conducted by the authors were identical to the methods used by EEB to analyze this type of data. Independent validation (see attached sheet) confirms that analyses were appropriate.

c. Discussion/Results: This study shows the following values for SY-83 (80% ai) effect on daphnids:

48-hour LC_{50} = 720 mg/l (practically nontoxic)
48-hour NOEL = 320 mg/l

d. Adequacy of Study:

1. Classification: Core

2. Rationale: SEP protocol; no major deviations noted.

3. Reparability: N/A

15. Completion of One-Liner for Study: Yes

16. CBI Appendix: N/A.

DATA EVALUATION RECORD

1. Chemical: Lactic acid (Propel)

2. Test Material: SY-83, 80% ai

3. Study/Action Type: Dietary LC_{50} Study - Bobwhite Quail (Colinus virginianus)

4. Study ID: A Dietary LC_{50} Study in the Bobwhite with SY-83. Final Report. Wildlife International Ltd. Project No. 203-101. 1984. Unpublished study submitted by Brea Agricultural Service, Inc., Stockton, CA. EPA Reg. No. 9018-A. EPA Acc. No. 265647.

5. Reviewed By: Allen W. Vaughan, Entomologist, EEB/HED — Signature: Allen W. Vaughan — Date: 11.13.87

6. Approved By: Norman Cook, Section Head, EEB/HED — Signature: Norman Cook — Date: 12.1.87

7. Conclusions:

The study is scientifically sound and fulfills the guideline requirement for a dietary study on an upland game bird using lactic acid. With an LC_{50} > 5620 ppm, lactic acid may be characterized as practically nontoxic to bobwhite quail (Colinus virginianus).

8. Recommendations: N/A.

9. Background:

This study was submitted in support of registration.

10. Discussion of Individual Tests or Studies: N/A

11. Materials and Methods (Protocols):

Ten bobwhite chicks, 10 days of age, were dosed at each treatment and control group. Birds were immature and no determination of sex could be made. Concentrations tested were 562, 1000, 1780, 3160, and 5620 ppm active ingredient. Birds were fed the appropriate test or control diet for 5 days followed by untreated feed for 3 days. Dietary test concentrations were not adjusted for purity of the test substance.

During acclimation and testing, all birds were housed indoors in thermostatically controlled brooding pens. Each pen contained 10 chicks. Test temperature in the brooding compartment was 100°F. Photoperiod was 17 hours of light during acclimation and the course of the study.

During acclimation birds were observed daily. Birds which exhibited abnormal behavior or physical injury were not used. After starting the test, birds were observed at least twice daily until the termination of the study. Signs of toxicity, abnormal behavior and mortality were recorded.

Individual body weights were measured at the initiation of the study and on days 5 and 8. Average estimated feed consumption for each test concentration group was determined for days 0 to 8.

Since there was less than 50 percent mortality at the highest concentration tested, an LC_{50} was not calculated. An estimation of the LC_{50} value was made by a visual inspection of the mortality data.

12. Reported Results:

There were no mortalities in the control group. All birds were normal in appearance and behavior throughout the test period.

There were no treatment-related mortalities or overt signs of toxicity at any concentration tested. There were two mortalities at the 562 ppm concentration. One bird at this level was noted on Day 3 with an impacted vent, and was found dead on Day 4. One additional bird was found dead on Day 6 with lesions of toe picking. At the 3160 ppm level one bird was found dead on Day 7. There was no treatment-related effect on body weight or feed consumption at any test concentration when treated groups were compared with controls.

13. Study Author's Conclusions/Quality Assurance:

The bobwhite dietary LC_{50} value of lactic acid for this study was determined to be greater than 5620 ppm, the highest concentration tested. The no-observed-effect concentration was 5620 ppm.

A quality assurance statement was included by Lee F. Doggett.

14. Reviewer's Discussion and Interpretation:

a. Test Procedures - Test procedures complied with those outlined in the HED Standard Evaluation Procedure for the avian dietary study. There were no problems in this regard.

b. Statistical Analysis - Analysis of data was by inspection.

c. Discussion/Results - The LC_{50} for the bobwhite quail (Colinus virginianus) is > 5620 ppm, the highest concentration tested, for the 80% ai lactic acid. This chemical may be characterized as practically nontoxic to bobwhite quail on a dietary basis.

d. Adequacy of the Study

1) Classification - Core

2) Rationale - SEP protocol; no major deviations noted

3) Reparability - N/A.

15. Completion of One-Liner for Study:

One-liner form completed.

16. CBI Appendix: N/A.

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DATA EVALUATION RECORD

1. Chemical: Lactic acid (Propel)

2. Test Material: SY-83, 80% ai

3. Study/Action Type: Dietary LC_{50} Study - Mallard Duck (Anas platyrhynchos)

4. Study ID: A Dietary LC_{50} Study in the Mallard with SY-83. Final Report. Wildlife International Ltd. Project No. 203-102. 1984. Unpublished study submitted by Brea Agricultural Service, Inc., Stockton, CA. EPA Reg. No. 9018-A. EPA Acc. No. 265649.

5. Reviewed By: Allen W. Vaughan, Entomologist, EEB/HED — Signature: Allen W. Vaughan — Date: 11.13.87

6. Approved By: Norman Cook, Section Head, EEB/HED — Signature: Norman Cook — Date: 12.1.87

7. Conclusions:

The study is scientifically sound and fulfills the guideline requirement for a dietary study on a waterfowl species using lactic acid. With an LC_{50} > 5620 ppm, lactic acid may be characterized as practically nontoxic to mallard duck.

8. Recommendations: N/A.

9. Background:

This study was submitted in support of registration.

10. Discussion of Individual Tests or Studies: N/A

11. Materials and Methods (Protocols):

Ten mallard ducklings, 8 days of age, were dosed at each treatment and control group. Birds were immature and no determination of sex was made. Concentrations tested were 562, 1000, 1780, 3160, and 5620 ppm active ingredient. Birds were fed the appropriate test or control diet for 5 days followed by untreated feed for 3 days. Dietary test concentrations were not adjusted for purity of the test substance.

During acclimation and testing, all birds were housed indoors in thermostatically controlled brooding pens. Each pen contained 10 birds. Test temperature in the brooding compartment was 100°F. Photoperiod was 17 hours of light during acclimation and the course of the study.

During acclimation birds were observed daily. Birds which exhibited abnormal behavior or physical injury were not used. After starting the test, birds were observed at least twice daily until the termination of the study. Signs of toxicity, abnormal behavior and mortality were recorded.

Individual body weights were measured at the initiation of the study and on days 5 and 8. Average estimated feed consumption for each test concentration group was determined for days 0 to 8.

Since there was less than 50 percent mortality at the highest concentration tested, an LC_{50} was not calculated. An estimation of the LC_{50} value was made by a visual inspection of the mortality data.

12. Reported Results:

There were no mortalities in the control group. All birds were normal in appearance and behavior throughout the test period.

There were no signs of toxicity, abnormal behavior, or mortality in any test group. All birds were normal in appearance and behavior throughout the test period.

When compared to the control, there was no effect on body weight or feed consumption throughout the test period.

13. Study Author's Conclusions/Ouality Assurance:

The mallard dietary LC_{50} value of lactic acid for this study was determined to be greater than 5620 ppm, the highest concentration tested. The no-observed-effect concentration was 5620 ppm.

A quality assurance statement was included by Lee F. Doggett.

14. Reviewer's Discussion and Interpretation:

a. Test Procedures - Test procedures complied with those outlined in the HED Standard Evaluation Procedure for the avian dietary study. There were no problems in this regard.

b. Statistical Analysis - Analysis of data was by inspection.

c. Discussion/Results - The LC_{50} for the mallard duck (Anas platyrhynchos) is > 5620 ppm, the highest concentration tested, for the 80% ai lactic acid. This chemical may be characterized as practically nontoxic to mallard duck on a dietary basis.

d. Adequacy of the Study

1) Classification - Core

2) Rationale - SEP protocol; no major deviations noted

3) Reparability - N/A.

15. Completion of One-Liner for Study:

One-liner form completed.

16. CBI Appendix: N/A.

DATA EVALUATION RECORD

1. Chemical: Lactic acid (Propel)

2. Test Chemical: SY-83, 80% ai

3. Study/Action Type: Acute Oral Toxicity Study - Bobwhite Quail (Colinus virginianus)

4. Study ID: An Acute Oral Toxicity Study in the Bobwhite with SY-83: Final Report. Project No. 203-103, Wildlife International Ltd., November 8, 1984. Unpublished study submitted by Brea Agricultural Service, Inc., Stockton, CA. EPA Reg. No. 9018-A. EPA Acc. No. 265650.

5. Reviewed By: Allen W. Vaughan, Entomologist, EEB/HED — Signature: Allen W. Vaughan — Date: 11.13.87

6. Approved By: Norman Cook, Section Head, EEB/HED — Signature: Norman Cook — Date: 12.1.87

7. Conclusions:

The study is scientifically sound and fulfills the guideline requirement for an acute oral toxicity test on an upland game bird. Lactic acid (80% ai), with an LD_{50} > 2250 mg/kg, may be characterized as practically nontoxic to the bobwhite quail.

8. Recommendations: N/A.

9. Background:

This study was submitted in support of registration.

10. Discussion of Individual Tests or Studies: N/A

11. Materials and Methods (Protocols):

The following was copied directly from the study.

"Apparently healthy, pen-reared, mature bobwhite, phenotypically indistinguishable from wild birds, were brought into the laboratory facility, examined for physical injury and acclimated for at least 14 days.

"Sixty bobwhite (30 cocks and 30 hens) were distributed by random draw into six groups of ten birds each, with five treatment groups and one control group. Feed was withheld from the control and test birds for at least 15 hours prior to oral administration of the experimental material.

"The experimental material was dispersed in distilled water and intubated directly into the crop via a stainless steel catheter. Each bird was individually weighed and dosed on the basis of milligrams of material per kilogram of body weight. The control birds received a corresponding volume of distilled water only. The ratio of experimental material to diluent was adjusted so that each bird received an approximately constant volume to body weight dose. The experimental material had a reported purity of 100%. The LD_{50} value reported is of the experimental material as received. Nominal dosages used in this study were 292, 486, 810, 1350, and 2250 milligrams of SY-83 per kilogram of body weight. Feed and water were available ad libitum following dosage. The birds received diet formulated to Wildlife International Ltd.'s specifications.

"The birds were housed indoors during the test period by treatment group in modified Georgia Quail Farm Breeder Units (Model No. 0010). Each pen measured approximately 78 X 51 X 23 cm. high and housed five cocks or five hens. External walls, ceilings, and floors were constructed of galvanized wire grid, while the common walls were constructed of galvanized sheeting.

"Average temperature for the study was 77°F ± 4°F (SD), with an average relative humidity of 74%. The photoperiod (maintained by a time clock) was seventeen hours of light per day throughout the study. The birds received approximately twelve footcandles of illumination. The light source was Chroma 50 fluorescent lights which closely approximate noon-day sunlight (noon-day sun - 4870° Kelvin, Chroma 50 - 5000° Kelvin).

"All birds were observed daily throughout the study, and a record was maintained of all mortalities and/or signs of toxicity and abnormal behavior. The LD_{50} value of SY-83 to the bobwhite was determined by inspection.

"Body weights were recorded individually at initiation, and by group on Days 3, 7, and at termination of the study on Day 14. Feed consumption was measured for Days 0-3, 4-7, and 8-14."

12. Reported Results:

There were no mortalities in the control group. All birds were normal in appearance and behavior throughout the test period.

There were no mortalities at any dosage tested. No overt signs of toxicity were observed during the course of the study. At the 292 mg/kg dose level one hen was observed on Day 5 with lesions of toe picking. All other birds appeared normal throughout the test period.

There was an apparent dosage related effect on body weight of males at the 1350 mg/kg and 2250 mg/kg dosages for Days 0-3. There appeared to be no effect on feed consumption at any dosage. Based on effects on male body weight at 1350 and 2250 mg/kg, the no-observed-effect dosage was 810 mg/kg.

13. Study Authors Conclusions/Ouality Assurance Measures:

No mortalities occurred at any dosage tested. It was determined by inspection that the LD_{50} value of lactic acid was greater than 2250 mg/kg, the highest dosage tested. Based on effects on male body weight, the no-observed-effect level was 810 mg/kg.

A quality assurance statement was included and signed by Lee F. Doggett.

14. Reviewer's Discussion and Interpretation:

a. Test Procedures - Test procedures complied with those outlined in the HED Standard Evaluation Procedure for the avian acute study. There were no problems in this regard.

b. Statistical Analysis - Analysis of data was by inspection.

c. Discussion/Results - The LD_{50} for the bobwhite quail is greater than 2250 mg/kg; lactic acid may be characterized as practically nontoxic on an acute oral basis.

d. Adequacy of the Study

1) Classification - Core.

2) Rationale - SEP protocol; no deviations noted

3) Reparability - N/A.

15. Completion of One-Liner for Study:

One-liner form completed.

16. CBI Appendix: N/A.

DATA EVALUATION RECORD

1. Chemical: Lactic acid (Propel)

2. Test Material: SY-83, 80% ai

3. Study/Action Type: Honey bee acute contact LD_{50}

4. Study ID: A Dermal Contact LD_{50} Study in Honey Bees with SY-83. Final Report. Wildlife International Ltd. Project No. 203-108. 1985. Unpublished study submitted by Brea Agricultural Service, Inc., Stockton, CA. EPA Reg. No. 9018-A. EPA Acc. No. 265646.

5. Reviewed By: Allen W. Vaughan
Entomologist
EEB/HED
Signature: Allen W. Vaughan
Date: 11.13.87

6. Approved By: Norman Cook
Section Head
EEB/HED
Signature: Norman Cook
Date: 12.1.87

7. Conclusions:

The study is scientifically sound and fulfills the guideline requirement for an acute contact toxicity study on honey bees. With an LD_{50} > 100.4 ug/bee, lactic acid may be characterized as practically nontoxic to honey bees.

8. Recommendations: N/A.

9. Background:

This study was submitted in support of registration.

10. Discussion of Individual Tests or Studies: N/A

11. Materials and Methods (Protocols):

Apparently healthy worker bees, less than three weeks of age, were collected from research colonies. Bees were then transferred directly to the testing laboratory. Test chambers were rolled paper containers. Each container was covered with a plastic petri dish through which a glass vial containing 50% sugar-water was inserted. This food source was available to the test bees throughout the study.

Test bees were maintained in the dark except during dosing and daily observations. Test temperatures ranged from 73 to 78° F.

Five treatment levels, 6.9, 12.8, 25.1, 50.2, and 100.4 ug/bee were tested along with a solvent control and a negative control. Two replicates were tested at each concentration with 50 bees per replicate. The solvent control bees received a volume of acetone equal to the largest volume used during the test.

Recently collected bees were immobilized with CO_2 to facilitate handling. Each bee was individually dosed on the abdomen with the appropriate test solution. Solvent control bees were dosed with 8 ul of acetone.

Observations on mortality and signs of toxicity were made at approximately 1/4, 3 1/2, 24, and 48 hrs after the completion of all dosing. The LD_{50} value for SY-83 was determined by inspection.

12. Reported Results:

Mortality rates in all five treatment groups were similar to those observed in the control and solvent control groups. Mortality did not appear to be treatment related. Mortality at the highest rate tested (100.4 ug/bee) was 13%.

13. Study Author's Conclusions/Quality Assurance:

The honey bee acute contact LD_{50} value for lactic acid for this study was determined to be greater than 100.4 ug per bee, the highest concentration tested.

A quality assurance statement was included by Lee F. Doggett.

14. Reviewer's Discussion and Interpretation:

a. Test Procedures - Test procedures complied with those outlined in the HED Standard Evaluation Procedure for the honey bee acute contact study. There were no problems in this regard.

b. Statistical Analysis - Analysis of data was by inspection.

c. Discussion/Results - The LD_{50} for the honey bee is greater than 100.4 ug/bee, the highest concentration tested, for the 80% ai lactic acid. This chemical may be characterized as practically nontoxic to honey bees.

d. Adequacy of the Study

1) Classification - Core

2) Rationale - SEP protocol; no major deviations noted

3) Reparability - N/A.

15. Completion of One-Liner for Study: N/A

16. CBI Appendix: N/A.